we know about metal-on-polyethylene, we know far less about the metal-on-metal, and I think the more we know about the basic information, the better off we are.

DR. YASZEMSKI: Thank you, Dr. Li.

Dr. Finnegan?

DR. FINNEGAN: I also think the answer is yes. However, I think that a number of these need to be included. Post-market surveillance; and I think the 522 needs to be negotiated for 5 to 10 years, because a good number of people sitting in the back of the room know that something can look good at 2 years and look catastrophic at 2-1/2 years, and they have already had this life experience with metal-on-metal. So I think that that needs to be prenegotiated that that is actually something they can do.

I think patient registration for the younger patients is essential; device tracking would be nice; and I agree with Dr. Li that testing guidelines definitely need to be set up.

DR. YASZEMSKI: Thank you, Dr. Finnegan.

Dr. Lyons?

DR. LYONS: Number 7, yes. Post-market surveillance, yes. Consider expanded test

guidelines, yes. Device tracking is probably a good idea.

DR. YASZEMSKI: Dr. Lyons, what do you think would be an appropriate duration for the post-market surveillance?

DR. LYONS: Well, Class II isn't an untracked class itself, either, so I think that 5 years is a nice number. I know that once you get to 5 years, everybody wants 10 years, but 2 years is a little bit on the brief side with the numbers that we have. If we had an option, I'd say up to 5. I wouldn't ask for anything more than that. I think that would be all right. But 5 would be a nice thought.

DR. YASZEMSKI: Also, before we move on to Dr. Wright, Dr. Finnegan, could I come back to you--you mentioned registering and following the young patients. Would you suggest an age range for what is "young" and should be included in that?

DR. FINNEGAN: Yes--under 75. No--again, Dr. Jacobs could probably help me with this. I don't know how long--it took 10 years for the hematopoietic tumors to show up. Is he still here?

DR. YASZEMSKI: Dr. Jacobs, would you mind commenting on this?

DR. FINNEGAN: Is there an age in the patients--in other words, was that more likely to happen if you were under 55 or 60 or more likely to happen if you were over 70?

DR. JACOBS: I don't think the studies are adequate enough that you can break out an age.

DR. FINNEGAN: Okay.

DR. JACOBS: Tom Schmalzried did that literature review. I don't know, Tom, if you have any additional information.

DR. YASZEMSKI: Dr. Schmalzried--age?

DR. SCHMALZRIED: I'm sorry. The problem is that in general, most of the follow-up that is available for those 10,000 or so cases is less than 5 years. There is a real small amount, a minimum number of patients, who have more than 10-year follow-up. That's one of the bit limitations of the data, because the latency periods for known carcinogens are longer than the person-years at risk that we have for these devices.

So that's a real problem. If you take traditional carcinogens--asbestos, tobacco, ionizing radiation--you are talking about decades latency.

DR. FINNEGAN: But your numbers were

pretty consistent in the two studies that after 10 years, there was a much higher risk.

DR. SCHMALZRIED: Oh, the risk goes up after 10 years, but you have to remember that this is an association, not a causation. If you are following anybody, once they go from 50 to 60 years of age, their risk goes up, and these are not adjusted--

DR. FINNEGAN: Right, it goes up. But if they are 90, we might not worry about it so much. I was looking for an upper limit.

DR. SCHMALZRIED: Well, if they start at 90, because their potential years of exposure are less, yes, that's correct.

DR. FINNEGAN: Yes. So there is no bottom number, and the top number is probably going to adjust as our life-expectancy adjusts--so, no.

DR. YASZEMSKI: Okay.

Dr. Wright?

DR. WRIGHT: Number 7 is yes.

I would recommend device tracking.

DR. WITTEN: Excuse me. Could I just provide a clarification about device tracking?

DR. YASZEMSKI: Please do.

DR. WITTEN: I am sorry to interrupt.

Device tracking is not for data collection on the devices. It is to allow the manufacturer to be able to reach the patient who has a given device in case they need to get back to that patient for that specific reason.

So I just want to be clear about the terms and what we are asking for, because there is a difference between what you might recommend if what you're looking for is prospective data collection versus making sure that a patient can be notified if there is a need to, and device tracking accomplishes the latter.

DR. YASZEMSKI: May I ask Dr. Witten, similar to the question was asked Dr. McGunagle before, how frequently is device tracking used at FDA?

DR. WITTEN: There are some tracked devices, but not a huge number. Actually, he might know the answer.

Do you know the answer to that?

DR. YASZEMSKI: Sorry, Dr. McGunagle. We are asking how frequently is device tracking used; and perhaps give an example of a device that has been tracked by the FDA.

DR. WITTEN: Well, I can tell you the one

example in our division, which is dura mater allograft is a tracked device.

DR. McGUNAGLE: The number of devices which are actually subject to tracking is relatively small; it is on the order of about 10. The list used to be considerably longer until the 1997 Amendments, where tracking was redefined in part in the statute, and we had to reassess the tracking list. That resulted in a great reduction.

DR. YASZEMSKI: Thank you, Dr. Witten and Dr. McGunagle.

MS. MAHER: Can I add something to the conversation?

DR. YASZEMSKI: Yes, please.

MS. MAHER: You are talking about post-market surveillance and going out 5 to 10 years. I think there are a couple of things that we should keep in mind. Number one, 5 to 10 years from now, many of these devices will potentially already be obsolete. Number two, we have an MDR procedure in place where we are following and we are required as a manufacturer to report adverse events to the agency, and that gets the information in there and actually does require us to keep track of and to notify people if the data shows that

there is an issue. We are also subject to the QSR or Quality System Regulations, and most of us to the Medical Devices Directive in Europe, which requires us to follow and track these types of issues as well and to come up with corrective actions and notifications if we find issues.

So in reference to postmarket surveillance for 10 years out, patient registries which have serious implications when it comes to patient privacy acts, you need to be careful how you are recommending these things and whether there are easier ways that are less burdensome to accomplish the same information.

DR. YASZEMSKI: Thank you.

DR. WRIGHT: Then, I am going to amend my answer. I'm going to say no for Number 7.

DR. YASZEMSKI: Okay. Thank you.

Any other comments, Dr. Wright?

DR. WRIGHT: No, thank you.

DR. YASZEMSKI: Dr. Cheng?

DR. CHENG: My answer is no, and I'll explain why. Just to follow up on Ms. Maher's comment, I don't think the device in 5 years is going to be outdated. I still put in the same hip I put in 5 years ago, and the hip that was put in

by my teachers 15 years ago is still being put in; so I don't think that in 5 years, it is going to be outdated. Unfortunately, our world doesn't change that fast.

I don't quite understand--my feelings on this issue are not much different from many of the people around the table, really--I have just heard Dr. Li, Dr. Peimer, and Dr. Aboulafia tell us that they felt the submission was premature or too early. If that's the case, I don't understand how you can give an answer of "yes" for the question in terms of answering this form.

I guess the question in my mind is how do we get the answers that you want and the data that you want as quickly as possible, with the highest level of confidence. In my opinion, that is to keep it as a Class III device and call for a PMA.

You are right, Sally, that if you leave it as it is right now, the devices will continue to go on the market through 510(k), but you aren't going to get the answers and the data that you want.

So if that is what we want, we should ask for it instead of just clearing it for approval; we're going to have a dozen devices out there in 10 years, and we're not going to have the answers to

the questions that we want, sitting here discussing around the table now.

That's why I would answer "no."

DR. YASZEMSKI: Thank you, Dr. Cheng.

Dr. Larntz?

DR. LARNTZ: Well, I'm afraid I am a conditional person, and my conditional person says that if the clinical studies which have been done, without even more data collection but analyzed properly, showed the convincing evidence that the device, metal-on-metal, were equivalent to metal-on-polyethylene, I would be quite satisfied to say that special controls should be the same as metal-on-polyethylene with additional testing related to the fact that we have metal in the device--and Dr. Li has certainly outlined that kind of testing.

So that is my condition; but if I don't have that assurance, and my leap of faith says, gee, I think I could analyze these data, and I bet they would come out okay--that's sort of my gut feeling--that's really my gut feeling, that it looks okay--nothing looks bad--I said that in my original presentation--but I don't have that information, so I gave my answer conditionally. If

I knew that the clinical studies analyzing the data that we have now--not premature, just analyzing the data that we have now, because I think that with longitudinal analysis, you could make a convincing case that you were equivalent; I can't make that with the kind of data analysis that was presented--but conditional on that, I would institute special controls the same as metal-on-polyethylene--and I don't know what those are, because--I just don't know--and with additional testing related to particularly using the metal device, particularly lab testing.

DR. CHENG: Could I follow up on that?

DR. YASZEMSKI: Yes, but before you start, Dr. Cheng--Dr. Larntz, yes or no?

DR. LARNTZ: Conditional--well, I guess I have to say no.

DR. YASZEMSKI: Thank you.

Dr. Cheng?

DR. CHENG: So if your answer is conditional, why approve it now? Why not approve it in 12 months or in 24 months? Basically, we have three studies here of unpublished data with less than 50 percent follow-up when the database was locked. Now, there is more data there if you

unlock the database that OSMA could present to the FDA. They could do the statistical analysis that you are requesting and bring it back to the committee and make a decision 12 months from now--or 6 months from now--and you'd have more data.

But we have three unpublished studies, and we have published studies on some of the contemporary devices that are cited here; but in 12 or 24 months, you are going to have more data, and you will be able to answer the question, as I said, with a higher level of confidence. So I just don't understand why you would down-classify it now at this point in time.

DR. YASZEMSKI: Dr. Larntz?

DR. LARNTZ: Yes, if I could follow up for just a second--and I don't disagree--I think the data may be there now, with appropriate analysis, to allow me to say--let me say I do want to make other point. I think patient registries are very ineffective because they are very hard to do. And this is a statistician talking, okay? So we have to be very careful when we think about patient registries. The difficulty in doing them is always underestimated--totally underestimated. They are

very, very hard to do.

I think we are better off allowing devices to be tracked and get our information from countries that have different health care systems that track patients better than we do. We don't do a very good job. So I really think--my opinion is that we almost have to give up on that, unless we are very, very intense about it, and I don't think many companies or Government agencies can be that intense over a long period of time. So that's my comment.

DR. YASZEMSKI: Thanks, Dr. Larntz.

I'm going to recognize Dr. Aboulafia in a moment, but may I ask Dr. Witten if the issue came up during Dr. Cheng's and Dr. Larntz' discussion about having to gather this data via the PMA process, and perhaps that would be more appropriate--but is it true or not true that the long-term data that we are discussing now may not come through that process because it would be at a 2-year point when each PMA would come through? Could you clarify that for us a little bit?

DR. WITTEN: Well, I'll just give you kind of a generic answer which will probably answer your question. If we called for PMAs, and a sponsor

submitted PMA for this kind of device, we would probably take it to an advisory panel like this one, and chances are we'd take it with a 2-year study, and then we would ask the panel what the panel recommended, and the panel may come out and say they think it should be approved and recommend a post-approval study. That is something that we have certainly done with other PMAs.

So I can't say exactly what we would do in this case, but that's what we have done with other orthopedic implants.

DR. YASZEMSKI: Thank you, Dr. Witten.

Dr. Aboulafia?

DR. ABOULAFIA: I would just say that I agree with that completely, and the comments that I made before still stick; and if my comments stick, then maybe the answer to the question is "no" and not "yes" as I initially said.

DR. YASZEMSKI: Do you want to change your answer?

DR. ABOULAFIA: Please.

DR. PEIMER: I have a question.

DR. YASZEMSKI: Dr. Peimer.

DR. PEIMER: I'm sorry, it's a point of information directed to Dr. Witten. If the

scenario you just described was a PMA and a postmarket study, why is it that what we are asking for is not a postmarket study in effect here--in other words, if we are looking for long-term data.

DR. WITTEN: Well, the mechanisms for getting postmarket data are different in the PMA and 510(k) process. So in the PMA, we have made these studies a condition of approval that the sponsors agree to. For these types of devices, these 510(k)s, Dr. McGunagle went over what our regulatory mechanisms were for getting additional data, which are basically, as he said, the MDR system and the Section 522. The MDR is the adverse event reporting, which isn't a prospective study, but it is a system for surveillance on types of adverse events.

And the Section 522 studies, which is the discretionary postmarket surveillance studies, which we can impose for up to a 3-year period post-clearance of the device.

So you get the information, and it is a different regulatory mechanism.

DR. PEIMER: In which case, I'd like to change my vote to "no."

DR. YASZEMSKI: Okay.

Are there any other comments?

MS. SHULMAN: Just for the record, we need a clarification on Dr. Larntz' vote--was it "yes" or "no"?

DR. LARNTZ: It was "no."

DR. YASZEMSKI: It would seem, then, that the majority of the panel is going to consider the answer to Question 7 "no," which would indicate that this would be a Class III device if we voted on it as is, and I would ask for clarification from FDA now. Given that, should we vote on the worksheet at this point, or should we go through the rest of it given the predominance of "no" answers to Question 7?

MS. SHULMAN: We'll continue with the worksheet and then vote on it as it is at the end.

DR. YASZEMSKI: Okay.

Numbers 8 and 9, we can skip, because they go to performance standards, and we don't have a performance standard.

Number 10: "For a device recommended for classification or reclassification into Class III, identifying the priority requiring premarket approval application (PMA) submissions."

This is a "high", "medium", "low" or "not

applicable" question. It is basically how quick do you want us to call for the PMAs to come in.

DR. FINNEGAN: What are the time frames?

MS. SHULMAN: There aren't any time frames.

DR. YASZEMSKI: Let's go around.

Dr. Aboulafia?

DR. ABOULAFIA: If I understand the question correctly, I would say it's a low priority. I think it is generated by industry, and industry can decide, and I wouldn't force the issue with industry one way or the other.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: I'd like to see industry apply, but I would leave it to industry to decide when to submit their PMA.

DR. YASZEMSKI: Dr. Li?

DR. LI: I'm sorry--could you repeat what this question means again?

MS. SHULMAN: It is basically how fast do you want us to go out and make the call for PMAs. When we make the call for PMAs, the companies will have 30 months to come in with their premarket approval application for us to review.

DR. LI: So these are companies that

already have 510(k) clearance?

MS. SHULMAN: Yes.

DR. LI: And so this would be how fast you want to make them come back and do a PMA?

MS. SHULMAN: Correct.

DR. PEIMER: So if you don't call for a PMA, nothing changes.

MS. SHULMAN: Correct.

DR. PEIMER: High; high priority.

DR. LI: I would like to make it medium priority. I'm sorry I was distracted; I think I finally understood Question 7. My apologies. It should be a "no" on my part for Question 7.

DR. YASZEMSKI: All right.

Dr. Finnegan?

DR. FINNEGAN: High priority.

DR. YASZEMSKI: Dr. Lyons?

DR. LYONS: Low priority.

DR. YASZEMSKI: Dr. Wright?

DR. WRIGHT: Medium.

DR. YASZEMSKI: Dr. Cheng?

DR. CHENG: Oh, I guess out of fairness to the companies, I think you should leave it in limbo; so I'd call for it as soon as you had the manpower to deal with it. If that's high priority

or medium, I don't know. I mean, it's not a life-threatening issue here; it has been going on for 25 years. But you may not have the manpower to deal with applications if it comes through--but I think you ought to deal with it as quickly as possible.

DR. YASZEMSKI: So that's a high priority for Dr. Cheng.

Dr. Larntz?

DR. LARNTZ: May I ask a question just to make sure? What if a company has a new metal-on-metal device, and we classify it officially as Class III--do they then go through a PMA process to get that approved, or if you haven't called for the PMAs, can they still use the 510(k) mechanism--since you haven't called for the PMAs for 25 years.

DR. YASZEMSKI: Dr. Witten?

DR. WITTEN: Right at the moment, anyone can come in with their application for a 510(k).

DR. LARNTZ: And until you call for the PMAs, this stays the same?

DR. WITTEN: Exactly.

DR. LARNTZ: Low priority.

DR. YASZEMSKI: Dr. Aboulafia?

DR. ABOULAFIA: Just a point of clarification. High priority means, if I understand it correctly, that you see that there is a major problem or major public health issue here, that this thing either needs to get off the 510(k) list or it should be approved and used everywhere, and replace everything we are already using. That's high priority.

Low priority, if I understand it correctly, means they are happy with the current system; it is okay with you; and if industry wants to take it to the next step, then it is up to them, but you wouldn't think that that is an overriding public health issue.

DR. YASZEMSKI: Dr. Witten or Ms. Shulman, is that accurate?

DR. WITTEN: Well, it really--no. I'd say it's really what Dr. Larntz summarized, which is that right now, we are at the status quo, and companies can come in with their 510(k)s. Once we call for PMAs, the ones who are on the market will need to come in with their PMA applications, if that's the direction we end up going in, and we'd have to review them, and they would either be on or off the market at the end of that period. And any

new person after that time, after the call for PMAs was issued, would need to come in with a PMA. But if we don't take an action, things will continue as they are. We won't be able to do that indefinitely, but things would be the status quo.

DR. YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: Isn't the problem also that all the questions we have about the science will just go unanswered, or there will be low motivation for them to be answered, until the PMA is put through?

DR. WITTEN: Well, I don't know--I can't answer that because there are so many people involved in medical device development besides just the firms themselves who are studying these. There are patients, there are physicians who are interested in their progress--there is lots of other scientific data, I hope, that is being generated aside from just the manufacturers themselves. So I really can't answer that.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: I have to agree with Dr. Finnegan. Unless the card is cold, other than major adverse events, I think we aren't getting the information. And here, in what I think has been a

good-faith effort to provide data over a short period of time, we don't have information that people, physicians, and statisticians honestly want to have and be able to feel good about what they are approving goes into the bodies of all of us.

So I think the best way to protect the public is to call for PMAs, and 25 years seems like enough. That seems like enough time. You could even drink fine wine, whoever drinks fine wine, after 25 years.

So call for the PMAs, and move forward, and if additional 5-year data are required based on the PMA, then, by gosh, ask for it and go forward. I think the public will be better-served with that than with letting things continue on and more devices come on the market with 510(k)s.

DR. YASZEMSKI: Dr. Aboulafia?

DR. ABOULAFIA: I'll make it very brief, and I promise I won't comment again about it. But as we talk about prioritizing things and whether this is a high priority, your statements are very good generic statements and are true of every device that has come before the FDA or ever will come before the FDA--the question is do you think it becomes a high priority because of some

information that you have, or is the status quo for now--is it reasonable to assume that there isn't an overriding public health issue or concern, and that the 100 hips that we do have information on lead you to believe that we need an answer to this question, and we should stop letting them put them in under the current system.

DR. FINNEGAN: I don't think it's that so much as the history of implants and the fact that this has been going on for 25 years. I think there are very few--maybe I'm wrong--but I think there are very few implants that have been 510(k)s for 25 years.

DR. YASZEMSKI: May I ask--we have had a lot of discussion on this--

DR. LARNTZ: Could I make one comment? I'm sorry.

DR. YASZEMSKI: Go ahead, Dr. Larntz.

DR. LARNTZ: I am in favor of a low priority because I think they are very close, and with a small amount of additional work, they could bring back this classification for the next panel meeting. It wouldn't take much, but it's a small amount. Since I can't approve it, I would make it a low priority, because I think if they think about

what we have said, they could come back very quickly, and it could easily be a Class II device.

DR. YASZEMSKI: Thanks, Dr. Larntz.

What I was about to ask--I am going to take you as the leader in what I was about to ask--that is, we have had a discussion about it. Let's walk around the panel one more time and say low, medium, or high.

I've got a low from Dr. Larntz.

Dr. Cheng?

DR. CHENG: I think they should call for it, so I would say high.

DR. YASZEMSKI: High from Dr. Cheng.

Dr. Wright?

DR. WRIGHT: Low.

DR. YASZEMSKI: Low from Dr. Wright.

Dr. Lyons?

DR. LYONS: Low.

DR. YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: High.

DR. YASZEMSKI: Dr. Li?

DR. LI: Can I ask one more question about this--I'm sorry.

DR. YASZEMSKI: Go ahead, Dr. Li.

DR. LI: My own personal conundrum here is

that there are two sets of devices in my mind. There are those devices that we know what they are and are 510(k)-cleared; and then, the second group of devices in my mind are the ones that we don't know what they are coming down the road, and we don't know in my mind all the biomechanical engineering aspects of what might make these devices good or bad.

So when you say--I guess my confusion in reading Number 10 is it says "Identify the priority for requiring premarket approval application submissions." The first time I read it through, I was going to say high because I thought that would pertain to all the new applications coming in; but if you're going to have to treat the ones that are out there the same way, so you would have to call immediately for the other--so it's all or nothing.

MS. SHULMAN: Correct. The ones out on the market would be treated as anyone coming into the market, and at the same time, they can undergo 510(k) or premarket notification until we call for PMAs, and then everyone would have to submit a PMA. For anyone new coming onto the market undergoing 510(k) now, there is always the option that it can be found not substantially equivalent because it is

that different and require a PMA a different way. However, we won't go there.

DR. YASZEMSKI: All right, Dr. Li--low, high, or medium?

DR. LI: High.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: In 30 months, the 24-month data will be 54 months, and we'll have our 5-year data; and if we call for it high, we've got to get it within 30 months. So I'm still high.

DR. YASZEMSKI: All right.

Dr. Aboulafia?

DR. ABOULAFIA: Low.

DR. YASZEMSKI: All right. I think we are 4-4, and I'm going to say low, and then we'll vote on it that way.

Let's go to Number 11.

MS. SHULMAN: Number 11. "Can there otherwise be reasonable assurance of its safety and effectiveness without restrictions on its sale, distribution or use, because of any potentiality for harmful effect or the collateral measures necessary for the device's use."

This is a prescription question, and if you answer "yes," it is not a prescription device;

if you answer "no," it is a prescription device.

DR. YASZEMSKI: Dr. Aboulafia?

DR. ABOULAFIA: No.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: No.

DR. YASZEMSKI: Dr. Li?

DR. LI: No.

DR. YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: No.

DR. YASZEMSKI: Dr. Lyons?

DR. LYONS: No.

DR. YASZEMSKI: Dr. Wright?

DR. WRIGHT: No.

DR. YASZEMSKI: Dr. Cheng?

DR. CHENG: No.

DR. YASZEMSKI: Dr. Larntz?

DR. LARNTZ: No.

DR. YASZEMSKI: All right. We have "no" for Question 11(a).

Now, Number 11(b).

MS. SHULMAN: Number 11 (b). "Identify the needed restrictions." These apply one on top of each other. The first one is "Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device."

Second, "Use only by persons with specific training or experience in its use." The third one, "Use only in certain facilities," and the fourth option is anything other that you would want to add.

DR. YASZEMSKI: Dr. Aboulafia?

DR. ABOULAFIA: I would put yes to the first part, only upon written and oral authorization of a practitioner authorized to use it; and for "Other" I would put as part of a prospective clinical trial.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: I agree. I would check the first one, and I would require specific training for use of total hips.

DR. YASZEMSKI: Okay. Dr. Li?

DR. LI: I'll defer to my clinical colleagues on that one.

DR. YASZEMSKI: Okay. Dr. Finnegan?

DR. FINNEGAN: The first one.

DR. YASZEMSKI: Dr. Lyons?

DR. LYONS: The first one, and by orthopedic surgeons trained in total hips but not necessarily metal-on-metal stuff.

DR. YASZEMSKI: Dr. Wright?

DR. WRIGHT: I'd say yes to the first two.

DR. YASZEMSKI: Thank you.

Dr. Cheng?

DR. CHENG: The first one as well.

DR. YASZEMSKI: Dr. Larntz?

DR. LARNTZ: The first two.

DR. YASZEMSKI: Okay. We have the first one or first two. Is it 4-4? I'm not sure if I heard 4. Everybody said the first one.

MS. SHULMAN: Everybody said the first one.

DR. YASZEMSKI: And how many people said the second one--raise your hands.

[A show of hands.]

DR. YASZEMSKI: One, two, three; so just the first one is the one we'll put and then vote on, and people can speak with their vote. Okay.

Ms. Shulman?

MS. SHULMAN: Now for the second form, the Supplemental Data Sheet.

The third question is, "Is the device an implant?" Yes.

The fourth question: "Indications for use prescribed, recommended, or suggested in the device's labeling that were considered by the advisory panel."

We can say what was discussed, the indications for use that were discussed in the petition, if you want to agree with that, and we can put it back up if you want.

DR. YASZEMSKI: Let's go around. Dr. Aboulafia?

DR. ABOULAFIA: Appropriate per petition.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: Per petition.

DR. YASZEMSKI: Dr. Li?

DR. LI: The same.

DR. YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: The same.

DR. YASZEMSKI: Dr. Lyons?

DR. LYONS: The same.

DR. YASZEMSKI: Dr. Wright?

DR. WRIGHT: Per petition.

DR. YASZEMSKI: Dr. Cheng?

DR. CHENG: The same.

DR. YASZEMSKI: Dr. Larntz?

DR. LARNTZ: Agreed.

DR. YASZEMSKI: Per petition, Ms. Shulman.

MS. SHULMAN: Okay.

DR. YASZEMSKI: Number 5.

MS. SHULMAN: Number 5: "Identification

of any risks to health presented by device." We can also say what was covered in the petition, or if you want to add any at this time.

DR. YASZEMSKI: Are there any that want to be added? If you remember, when we answered Question 1, there was a list of risks that we didn't add to at that time.

Dr. Aboulafia, per petition?

DR. ABOULAFIA: I would neither add nor subtract.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: No change.

DR. YASZEMSKI: Dr. Li?

DR. LI: No change.

DR. YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: Per panel.

DR. YASZEMSKI: Dr. Lyons?

DR. LARNTZ: No change.

DR. YASZEMSKI: Dr. Wright?

DR. WRIGHT: No change.

DR. YASZEMSKI: Dr. Cheng?

DR. CHENG: No change.

DR. YASZEMSKI: Dr. Larntz?

DR. LARNTZ: No change.

DR. YASZEMSKI: Per petition and per panel

discussion.

MS. SHULMAN: Number 6. "Recommended advisory panel classification and priority." We decided that that was Classification III, and the priority--

DR. YASZEMSKI: We said low.

MS. SHULMAN: --low.

DR. YASZEMSKI: Okay. Number 7.

MS. SHULMAN: Number 7 does not apply because it is in Class III.

DR. YASZEMSKI: Number 8.

MS. SHULMAN: Number 8. Summary of information, including clinical experience or judgment, upon which classification recommendation is based."

We can say, if you wish, what was discussed today in the panel meeting.

DR. YASZEMSKI: Per panel discussion.

We'll go around for a yea. Dr. Aboulafia?

DR. ABOULAFIA: Yea.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: Yea.

DR. YASZEMSKI: Dr. Li?

DR. LI: Yea.

DR. YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: Yea.

DR. YASZEMSKI: Dr. Lyons?

DR. LYONS: Yea.

DR. YASZEMSKI: Dr. Wright?

DR. WRIGHT: Yea.

DR. YASZEMSKI: Dr. Cheng?

DR. CHENG: Yea.

DR. YASZEMSKI: Dr. Larntz?

DR. LARNTZ: Yea.

MS. SHULMAN: Number 9 is the restrictions question again. "Identification of any needed restrictions on the use of the device." And we had--it is a prescription device only--I don't remember--did we pick training, or not? No. Prescription device. Was there anything else that should be added there?

DR. YASZEMSKI: Dr. Aboulafia?

DR. ABOULAFIA: I wondered--I said that I wanted these put in as part of a prospective clinical trial. No one took up on that. Is that appropriate/not appropriate, or is it worthwhile/not worthwhile?

DR. YASZEMSKI: Let's go around.

Dr. Peimer, should we include as part of a clinical trial?

DR. PEIMER: No.

DR. YASZEMSKI: Dr. Li?

DR. LI: I'm sorry--

DR. YASZEMSKI: Should we include a restriction that they put in as part of a prospective clinical trial?

DR. LI: That they have to have a prospective clinical trial?

DR. YASZEMSKI: Yes.

DR. LI: I'll say yes.

DR. YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: Maybe--I'll say yes.

DR. YASZEMSKI: Dr. Lyons?

DR. LYONS: No.

DR. YASZEMSKI: Dr. Wright?

DR. WRIGHT: No.

DR. YASZEMSKI: Dr. Cheng?

DR. CHENG: I'm not sure I understood the question. Could you clarify it?

DR. YASZEMSKI: We're discussing whether we should add under Number 9, "needed restrictions on the use of the device," whether we should put in there before we vote on this sheet that it can be put in only under the auspices of a prospective clinical trial.

DR. LI: I misunderstood the question, then. So this means that you're going to do a prospective clinical trial before sale?

DR. WITTEN: Can I make some clarification--

DR. YASZEMSKI: Please do, Dr. Witten.

DR. WITTEN: 510(k) devices are not experimental devices, so what you would be saying is that you wouldn't even think they should be allowed on the market as 510(k)s, but they should only be allowed as part of an Investigational Device Exemption.

DR. YASZEMSKI: All right. We'll withdraw that, we'll withdraw that. Thank you.

So we'll move to Dr. Peimer. If the needed restrictions on the use were just the first box, that they are prescription devices by a licensed physician.

DR. PEIMER: I would like to take one more go at the panel and see if I can pick up one vote. On training in orthopedic total hip implants, I agree with Dr. Lyons--not specifically metal-on-metal, but that you have specific training in the hip implants rather than just per prescription.

DR. YASZEMSKI: May I ask Dr. Witten for your discussion on the relationship of FDA to medical licensure for the States? That may clarify this issue.

DR. WITTEN: Yes. You can recommend that the person be appropriately trained, but to say that they would be appropriately trained orthopedists would be beyond--

DR. PEIMER: No, i didn't say orthopedists, no--appropriately trained in hip prosthetic surgery.

DR. YASZEMSKI: I might also mention that for the metal-on-polyethylene hips, that's not a requirement at the current time, so this would be different than the requirements that are out there for existing total hip arthroplasties.

MS. SHULMAN: Can I clarify something, also? That added restriction can be what you're saying, but it is also used a lot of times in the context of the company providing training to the surgeon before its use; so it would be a part of either the approval process or part of a special control for the company to come and provide training. So it can also be used that way, and a lot of times, that's what that part means, too.

DR. YASZEMSKI: I might ask for other input from the panel, but I would say that my view on this is that that would be covered by existing medical licensure laws and that it would be unlikely that someone other than an orthopedic surgeon would be doing this.

Are there other comments from the panel on that--I wouldn't think we would need to put that in specifically here.

DR. PEIMER: Specific device implantation has not, at least in my part of New York State, been regulated in that way, and if there are some radically new devices or procedures, they may catch the attention of credentialing boards, but I think for Mr. Dacey's hip, I'd like him to feel that he's getting someone who is trained in hip implantation surgery and not someone, orthopedic surgeon or otherwise, who has never put a hip in before. I don't think it's unreasonable to ask for. I think it's one of those things that I would like to believe--I tend to believe that by spillover, it will work its way into metal-on-plastic hips as well.

DR. YASZEMSKI: Other panel comments?

Dr. Aboulafia?

DR. ABOULAFIA: I just think that falls out of the purview of FDA. I am legally allowed to administer a general anesthetic. The people who make the anesthesia machines don't have to put that I shouldn't be doing it. It's not something that's in the purview of the FDA. Hand surgery isn't regulated--they can't say who is allowed to put in certain implants in the hand or anything else. So it's more in the purview of delineation of privileges than it is something that the FDA can require.

DR. PEIMER: In which case--

DR. ABOULAFIA: In other words, there is no other--

DR. PEIMER: --why isn't that on two of these sheets?

DR. ABOULAFIA: They're looking for special training, like is this something that is so different--like when Syntheze first came out with implants, they wanted to specially train doctors to understand the idea of compression plating; that was something different than what had been done previously, at least in their view. Whereas this--do you think someone who knows how to do a total hip needs special training from the company,

or not? If you don't, the answer is "no." If you think this is so different than any other total hip--okay.

DR. YASZEMSKI: Let's finish the rest of the panel.

Dr. Finnegan?

DR. FINNEGAN: I would actually like to address that, because I think in the hands of people who designed this and who are very good at it, there have been some interesting problems, and I think the problem of clearance in particular, which is not necessarily as specific a problem with metal-on-polyethylene, probably does warrant some kind of basic training in the implant, and I would certainly support that.

DR. YASZEMSKI: Dr. Lyons?

DR. LYONS: My opinion draws from the fact that I still think Number 7 should be "yes" and that's because as an engineering, I think I have a very good comfort level with this product. As a physician, I have a problem with polyethylene debris giving me trouble, and I want an alternative. I think that the data makes me comfortable there is an alternative--but it's a new device, and I think that you ought to let the new

surgeons know if it is something different than they are using that there are qualifiers, things you have to watch for, impingement, which will lead to loosening that would lead to metallosis.

There are issues there, so from my perspective, if I am looking to go ahead and down-class it to II, I want to upgrade my warning or somehow get a message to the surgeons.

However, for the rest of the panel who might keep Number 7 "no", I understand exactly what you are saying. My precondition is that I want to down-class it because I have a good comfort level with the technology. That was the only reason.

So I would still recommend some way on a product, if it is down-classed, to tell the surgeons in that process that it is not the same as what you are used to. That's why I'd like to have some kind of notice.

DR. YASZEMSKI: Thank you.

Dr. Wright?

DR. WRIGHT: Can I just say "no"?

DR. YASZEMSKI: That's fine.

Dr. Cheng?

DR. CHENG: I would say no.

DR. YASZEMSKI: Dr. Larntz?

DR. LARNTZ: No.

DR. YASZEMSKI: Okay. I think the major is "no" for the second one.

Then, the people who want "yes" can vote as your conscience dictates when it comes time to vote on the proposal.

Go ahead, Ms. Shulman.

MS. SHULMAN: Question 10, we skip, because that's just for Class I or certain Class II devices.

Question 11. "Existing standards applicable to the device, device subassemblies (components) or device materials (parts or accessories)."

I believe there was a list, too, wasn't there, on one of the slides of the standards?

DR. YASZEMSKI: Yes. There was a list of ASTM standards that Mr. Steigman presented that applied to it as voluntary standards, and if voluntary standard inclusions are okay, we can include them as per his presentation.

MS. SHULMAN: Correct.

DR. YASZEMSKI: Thank you.

Now we will proceed with the second open public hearing session of this meeting. I'll ask

at this time that all persons addressing the panel come forward and speak clearly into the microphone as the transcriptionist is dependent on this means of providing an accurate record of the meeting. We are requesting that all persons making statements during the open public hearing of the meeting disclose whether they have financial interests in any medical device company.

Before making your presentation to the panel, in addition to stating your name and affiliation, please state the nature of your financial interest.

At this time, is there anyone who wishes or needs to address the panel?

[No response.]

DR. YASZEMSKI: Seeing none, I would like to specifically ask if any of the members of OSMA would like to take another opportunity to address the panel.

[No response.]

DR. YASZEMSKI: Seeing none, we have completed the worksheet and Supplemental Data Sheet, and we will now proceed to voting upon them.

I'll remind everybody that the industry and consumer representatives as well as the chair

do not vote, and the chair votes only in the event of a tie.

I will ask at this time if there is a motion to accept the Classification Worksheet as we have just filled it out, with a recommendation of Class III.

Dr. Lyons, could I ask you to make a motion?

DR. LYONS: I would actually make the motion to declassify to II.

DR. YASZEMSKI: Okay. I neglected to remember that you were in the minority--pardon me--and it would be inappropriate to ask you to make the motion.

DR. LYONS: Yes; I'd just as soon not.

DR. YASZEMSKI: Pardon me for asking you to do that.

I'd like to ask for that motion from one of the members of the majority.

DR. CHENG: So moved.

DR. YASZEMSKI: Dr. Cheng, would you care to make that motion?

DR. CHENG: I move that you approve it in its present form.

DR. YASZEMSKI: Thank you.

Is there a second for the motion?

DR. PEIMER: Second.

DR. YASZEMSKI: The motion has been moved and seconded to vote for Class III classification as described in the classification and supplemental worksheets that have just been filled out.

I will ask all the members to vote now, and we'll start with Dr. Larntz.

DR. LARNTZ: Aye.

DR. YASZEMSKI: Dr. Larntz, aye.

Dr. Cheng?

DR. CHENG: Yes.

DR. YASZEMSKI: Dr. Wright?

DR. WRIGHT: Yes.

DR. YASZEMSKI: Dr. Lyons?

DR. LYONS: I am in a tiny minority; no.

DR. YASZEMSKI: It's important.

DR. FINNEGAN: It's an important minority.

DR. YASZEMSKI: Dr. Finnegan?

DR. FINNEGAN: Yes--I mean, no. I vote against the amendment.

DR. YASZEMSKI: You vote against.

Dr. Li?

DR. LI: In favor.

DR. YASZEMSKI: Dr. Peimer?

DR. PEIMER: In favor.

DR. YASZEMSKI: And Dr. Aboulafia?

DR. ABOULAFIA: Yes to the motion.

DR. YASZEMSKI: The vote is 5-2 in favor of the motion. The recommendation of the panel is that the metal-on-metal device be classified into Class III.

We'll now take a 15-minute break and proceed with the closed session.

[Whereupon, at 3:34 p.m., the open session was concluded, to reconvene in closed session at 3:56 p.m.]

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CERTIFICATE

I, **ANNE E. HAYES,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

Anne E. Hayes

ANNE E. HAYES